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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,294	12/27/2001	Toshiyuki Sakai	442P090	9019
42754	7590	06/30/2005	EXAMINER	
NIELDS & LEMACK 176 EAST MAIN STREET, SUITE 7 WESTBORO, MA 01581			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 06/30/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,294

Applicant(s)

SAKAI ET AL.

Examiner

MISOOK YU, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Exhibit C.

RS

DETAILED ACTION

Applicant's reply filed on 14 April 2005 is acknowledged. Claims 1 and 5 are amended. Claims 1 and 3-5 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Office action contains new objection to the claims.

Information Disclosure Statement

The information disclosure statement filed 03/12/2002 contains two WO documents, i.e. WO 99/50412, and WO 99/61610 that are in Japanese and German respectively. Applicant argues that the IDS was filed in compliance with 37 CFR 1.97 and 1.98 and the examiner is obligated to consider the two submitted documents to the full extent according to MPEP 609, although they are not in English. The instant application, which is filed under 371, is subjected to the laws and regulations governing the U.S. patent applications.

The following is an excerpt of MPEP 609.

37 CFR 1.97. Filing of information disclosure statement.

(a) In order for an applicant for a patent or for a reissue of a patent to have an information disclosure statement in compliance with § 1.98 considered by the Office during the pendency of the application, the information disclosure statement must satisfy one of paragraphs (b), (c), or (d) of this section.

(b) An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:

(1) Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);

(2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;

(3) Before the mailing of a first Office action on the merits; or

(4) Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

(c) An information disclosure statement shall be considered by the Office if filed after the period specified in paragraph (b) of this section, provided that the information disclosure statement is filed before the mailing date of

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any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application, and it is accompanied by one of:

- (1) The statement specified in paragraph (e) of this section; or
- (2) The fee set forth in § 1.17(p).

(d) An information disclosure statement shall be considered by the Office if filed by the applicant after the period specified in paragraph (c) of this section, provided that the information disclosure statement is filed on or before payment of the issue fee and is accompanied by:

- (1) The statement specified in paragraph (e) of this section; and
- (2) The fee set forth in § 1.17(p).

(e) A statement under this section must state either:

(1) That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

(2) That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

(f) No extensions of time for filing an information disclosure statement are permitted under § 1.136. If a bona fide attempt is made to comply with § 1.98, but part of the required content is inadvertently omitted, additional time may be given to enable full compliance.

(g) An information disclosure statement filed in accordance with section shall not be construed as a representation that a search has been made.

(h) The filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).

(i) If an information disclosure statement does not comply with either this section or § 1.98, it will be placed in the file but will not be considered by the Office.

37 CFR 1.98. Content of information disclosure statement.

(a) Any information disclosure statement filed under § 1.97 shall include:

(1) A list of all patents, publications, applications, or other information submitted for consideration by the Office;

(2) A legible copy of:

(i) Each U.S. patent application publication and U.S. and foreign patent;

(ii) Each publication or that portion which caused it to be listed;

(iii) For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion; and

(iv) All other information or that portion which caused it to be listed; and

(3) (i) A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language. The concise explanation may be either separate from applicant's specification or incorporated therein.

(ii) A copy of the translation if a written English-language translation of a non-English-language document, or portion thereof, is within the possession, custody, or control of, or is readily available to any individual designated in § 1.56(c).

(b) (1) Each U.S. patent listed in an information disclosure statement must be identified by inventor, patent number, and issue date.

(2) Each U.S. patent application publication listed in an information disclosure statement shall be identified by applicant, patent application publication number, and publication date.

(3) Each U.S. application listed in an information disclosure statement must be identified by the inventor, application number, and filing date.

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(4) Each foreign patent or published foreign patent application listed in an information disclosure statement must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application.

(5) Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.

(c) When the disclosures of two or more patents or publications listed in an information disclosure statement are substantively cumulative, a copy of one of the patents or publications may be submitted without copies of the other patents or publications, provided that it is stated that these other patents or publications are cumulative.

(d) A copy of any patent, publication, pending U.S. application or other information, as specified in paragraph (a) of this section, listed in an information disclosure statement is required to be provided, even if the patent, publication, pending U.S. application or other information was previously submitted to, or cited by, the Office in an earlier application, unless:

(1) The earlier application is properly identified in the information disclosure statement and is relied on for an earlier effective filing date under 35 U.S.C. 120; and

(2) The information disclosure statement submitted in the earlier application complies with paragraphs (a) through (c) of this section.

As the above excerpt indicates, MPEP 609 does not stipulate that the U.S. Patent Office is obligated to hire a foreign language translators for the IDS not in English if the case is filed under 371. In fact, MPEP 609 indicates that the IDS filed on 3/12/02 failed to comply 37 CFR 1.98 (a) (3) (i), and (ii) because applicant does not provide the Office the translation of the two documents that are written in foreign languages.

As stated in the previous Office action, it is noted that both documents are cited in the ISR. Therefore both documents have been considered to the extent (abstract, sequence listings, and some drawings) that the Examiner could understand after examining the ISR. It is also noted that the ISR has been considered by the Office.

New Claim Objections

Claim 1 is newly objected to because of the following informalities: The sub-numbering of claim 1 is to be preserved throughout the prosecution. When sub-number(s) of claim is canceled, the remaining sub-number must not be renumbered. When new sub-numbers are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously

presented. Re-numbering (3) in claim 1 to (2) would obviate this objection. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Maintained

Claims 1 and 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recite "under a stringent condition" but it is clear what the metes and bounds are.

Applicant argues that those skilled in the art will be able to determine what constitutes stringent conditions, and reference is made to the paragraph bridging pages 10, and 11 of the specification, where suitable stringent conditions are disclosed.

The following is the paragraph bridging pages 10, and 11 of the specification:

(1-3) DNA that hybridizes to DNA comprising the base sequence as set forth in SEQ ID NO: 1 of the sequence listing under a stringent condition and that has a p51 promoter activity is also encompassed in the scope of the present invention. Such hybridizing DNA mutants include DNA sequences partially altered by the mutation, deletion, ligation etc. of DNA fragments by site-directed mutagenesis, mutagen-treated random mutation, cleavage with restriction enzymes. The degree to which these DNA mutants hybridize to the coding gene as set forth in SEQ ID NO: 1 is a stringent condition: for example, the above membrane is incubated in a hybridization solution (50 mM Tris-HCl, PH 7.5, 1 M sodium chloride, 1% sodium dodecylsulfate, 10% dextran sulfate, 0.2 mg/ml yeast RNA, 0.2 mg/ml salmon sperm DNA) at 650C for one hour as prehybridization, then a radioisotope-labeled cDNA fragment is added to one million dpm/ml in terms of the amount of radioisotope and incubated at 650C for 16 hours as hybridization, and subsequently the membrane is washed in a 2 x SSC solution (300 mM sodium chloride, 30 mM trisodium citrate) containing 0.1% sodium dodecylsulfate at 650C for 30 minutes, followed by autoradiography analysis to confirm hybridization on an X-ray film.

What would hybridizes to the instant SEQ ID NO:1 would depend on the hybridizing conditions, and in turn determines the claimed property boundary sought by the patent if granted. The specification as originally filed does not define the claimed stringent conditions. Rather, the specification as originally filed gives an example of stringent conditions. Since the specification does not define the stringent conditions with

a reasonable degree of certainty, the scope of the claimed invention encompassed by the limitation "under stringent condition" in claim 1 is unclear.

All dependent claims are also rejected because the scope encompassed by the dependent claims includes the hybridizing molecules under the unclear conditions.

Claims 1 and 3-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 3-5 are interpreted as drawn to a genus of isolated genes hybridizing to SEQ ID NO: 1 under an unspecified stringent condition, wherein said genus has p51 promoter activity, wherein said genus is in a recombinant plasmid (claim 3), in a transformant (claim 4).

The applicable standard for the written description requirement can be found: MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Prove Inc., 63 USPQ2d 1609; Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111; and University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC 2004).

Applicant argues that the amended claims now satisfy the written description requirement.

The amendment and the argument have been fully considered but found unpersuasive.

First, the base claims 1 as currently construed still reads on the entire p51 gene comprising SEQ ID NO:1 plus an native enhancer region controlling the transcription of said coding region because Darnell et al., (1990, Molecular Cell Biology, 2nd Edition, pages 344-345 only) teach that a gene also includes enhancer. However, the specification does not disclose any enhancer element of p51 gene.

Further, the structure of the claimed genus of genes with p51 promoter activity is not adequately described since the limitation "under stringent condition" is not clear as to structural nature of the claimed genes. Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleic acid molecules, given that the specification has only one species, i.e. either SEQ ID NO: 1 or 2 (note SEQ ID NO:2 is a slightly longer than SEQ ID NO:1, otherwise identical). Therefore, only isolated nucleic acid comprising SEQ ID NO:1 and 2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 101, Withdrawn

The rejection of claims 1 and 5 under 35 USC 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102, Maintained

Claims 1, 3, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Acc. No. AQ168656 (16 October, 1998).

Claims 1, 3, 4, and 5 are interpreted drawn to a nucleic acid sequence hybridizing to SEQ ID NO:1, wherein the claimed nucleic acid has p51 promoter activity (claim 1), wherein said nucleic acid sequence in a recombinant plasmid (claim 3), said recombinant plasmid in transformant (claim 4), a nucleic acid probe (claim 5) are claimed.

Applicant argues that the amended claims recite only SEQ ID NO: 1, and the prior art of record does not contain TATA box, which exist in SEQ ID NO: 1 and which is need for the p51 promoter activity, and the instant specification at page 8 explains TATA box in detail.

These arguments have been fully considered but found unpersuasive. Contrary to applicant's argument that the nucleic acid sequence disclosed in GenBank Acc. No. AQ168656 does not contain TATA box, the nucleotide sequence disclosed in GenBank Acc. No. AQ168656 does contain TATA box. Note the previously provided sequence alignment (Exhibit A), which shows that the nucleotide sequence of "TATAAT" at Row 6, right half of page 2 of the sequence alignment (Exhibit A). Voet et al., (1990, Biochemistry, John Wiley & Sons, page 865) teaches that "TATAAT" is a classic, so-called TATA or Goldberg-Hogness box. As for applicant argument with the amended claim 1 reciting SEQ ID NO: 1, SEQ ID NO: 2 is 284 nucleotides longer than SEQ ID NO: 1 at its 3' end, however, otherwise identical (note the sequence alignment of instant

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SEQ ID NO: 1, and 2, i.e. Exhibit C). Since the previously provided Exhibit A shows that GenBank Acc. No. AQ168656 is 90.9 % identical from nucleotides 672 to 1171 of the instant SEQ ID NO: 2, the instant claims reciting SEQ ID NO: 1 does not change any fact pattern.

As stated in the previous Office action, GenBank Acc. No. AQ168656 teach a nucleic acid with 90.6 % similarity from nucleotide #672 to 1171 of instant SEQ ID NO: 2 (and SEQ ID NO: 1). Note previously provided Exhibit A, and Exhibit C aligning instant SEQ ID NO: 1, and 2), and also teaches that the clone is in plasmid vector pBeloAAC11, which is a BAC clone in E. Coli strain DH10B. Thus, the strain of E. coli is a transformant.

Claims 1, and 5 **remain rejected** under 35 U.S.C. **102(b)** as being anticipated by Yang et al., (1998, Molecular Cell, vol. 2, pages 305-316).

Claims 1 and 5 are interpreted drawn to a nucleic acid sequence hybridizing to SEQ ID NO:1, wherein the claimed nucleic acid has p51 promoter activity.

Applicant argues that GenBank Acc. No. AF124528 is published after the effective filing date of the instant application, thus not a prior art, and Yang et al., do not disclose any of the DNA sequence, nor do Yang et al., disclose the p51 promoter sequence of SEQ ID NO: 1. The specification at Example 1 demonstrates SEQ ID NO: 1 exhibits the p51 promoter activity.

These arguments have been fully considered but found unpersuasive. As the previously provided Office action indicates, claims 1, and 5 are not rejected over

GenBank Acc. No. AF124528. Rather, GenBank Acc. No. AF124528 is cited to provide the evidence that "p63", and the instantly recited limitation "p51" are the identical gene.

As for applicant's argument that Yang et al., do not disclose DNA sequences, this argument is seen as not commensurate in scope of the claims because the scope is not limited SEQ ID NO: 1 but also includes a gene that hybridizes to SEQ ID NO: 1 under an unspecified stringent condition.

As stated in the previous Office action, Yang et al., at Fig. 2A teach a genomic structure of p63 gene encoding at least 6 different splicing variants. It appears that p51 gene is same as p63 gene because GenBank Acc. No. AF124528 (Jan. 04, 2001) teaches that the C-terminal end of instant SEQ ID NO:2, more specifically nucleotides #5462 to #5960 of SEQ ID NO:2 is exon 1 of p63 (note Exhibit B) shown in Fig. 2A of Yang et al. Yang et al., at page 314 under the heading "Cloning of p63" teaches a 120 kb clone that contains all of the human p63 gene, also teach at page 308, right column "the human p63 PAC clone as a probe" is used to map the gene to 3q27-29 (note also Fig. 3). Although Yang et al., do not list the nucleic acid sequence of the instant claimed promoter and/or 5' untranslated region sequence, it appears that the instantly claimed gene sequence and the sequence of p63 of the art are same. The court, especially Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989) stated that in order to be the same product, the art does not have to list the chemical composition of the product. Here, the human 120 kb clone used to map the p63 gene to 3q27-29 (note Fig. 3) appear to contain all of instantly claimed p51 gene including the promoter region, or the 5'-untranslated region. The Office does not have the facilities and

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resources to provide the factual evidence needed in order to establish that the nucleic acid of possess the same functional characteristics of the instantly claimed nucleic acid. In the absence of evidence to the contrary, the burden is on the applicant to prove that the instantly claimed gene hybridizing to SEQ ID NO: 1 is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). Furthermore, the preamble recitation of probe in claim 5 is merely suggestive of an intended use and is not given patentable weight for purposes of comparing the claim with the prior art. The claim reads on the nucleic acid *per se*.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642

Misook Yu 6-27-05

Exhibit C
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QY 4021 CCTTCTATTTAGGTCATCTATATTTGCTAATAGCAGGGAAGAACCCAAACTCTTTAACT 4080
DB 1656 CCTTCTATTTAGGTCATCTATATTTGCTAATAGCAGGGAAGAACCCAAACTCTTTAACT 1597
QY 4081 GCAATTAACAAATCTATAATTAATTAAGTAAAGCAATCTTCCCTTTAAGTTTAACTTTTG 4140
DB 1596 GCAATTAACAAATCTATAATTAATTAAGTAAAGCAATCTTCCCTTTAAGTTTAACTTTTG 1537
QY 4141 TGGAGCAAGCTGTTGATTTGGCTGGGGCTCAGGCCGGGCTGTTTGGGAATTTCAAAAT 4200
DB 1536 TGGAGCAAGCTGTTGATTTGGCTGGGGCTCAGGCCGGGCTGTTTGGGAATTTCAAAAT 1477
QY 4201 CACAGATGTTAGCGCTCTCGGGCTAAGTAAGGAAGCAAGATGTCAGATTTTAAATAGCT 4260
DB 1476 CACAGATGTTAGCGCTCTCGGGCTAAGTAAGGAAGCAAGATGTCAGATTTTAAATAGCT 1417
QY 4261 TCTCCCTTCCATCTCGGCTGAAGCAACAAATTTCTCGAAGGCTTTAGATTTTGGAGT 4320
DB 1416 TCTCCCTTCCATCTCGGCTGAAGCAACAAATTTCTCGAAGGCTTTAGATTTTGGAGT 1357
QY 4321 TAGATTTACTTACAGGGAATGTCAAATTTCTCGAAGGCTTTAGATTTTGGAGTCTCAAC 4380
DB 1356 TAGATTTACTTACAGGGAATGTCAAATTTCTCGAAGGCTTTAGATTTTGGAGTCTCAAC 1297
QY 4381 TTTGACATCTACTGATCTCACTATTTACAGGTGTCGTGACTAGGGGCTGAAGGA 4440
DB 1296 TTTGACATCTACTGATCTCACTATTTACAGGTGTCGTGACTAGGGGCTGAAGGA 1237
QY 4441 AGATGTCAATCTCACTATTTAGTCACTGTCGTGACTAGGGGCTGAAGGA 4500
DB 1236 AGATGTCAATCTCACTATTTAGTCACTGTCGTGACTAGGGGCTGAAGGA 1177
QY 4501 TTGGAGTCTATCTTCACTAGCTTCTGAATTTCTGAATTTTCAATTTTCAAAATCCAA 4560
DB 1176 TTGGAGTCTATCTTCACTAGCTTCTGAATTTCTGAATTTTCAATTTTCAAAATCCAA 1117
QY 4561 ACCAGGTAAGTTTACAGGCCATTTCAAGGAATTAATTTTGGTGTAGACTT 4620
DB 1116 ACCAGGTAAGTTTACAGGCCATTTCAAGGAATTAATTTTGGTGTAGACTT 1057
QY 4621 TCCTGATATTACACTGATTTGGGATATATGAACAAATTTTATGTTTCTTTCGAAGTAG 4680
DB 1056 TCCTGATATTACACTGATTTGGGATATATGAACAAATTTTATGTTTCTTTCGAAGTAG 997
QY 4681 GTCAAGTCAAAGCAAAACCAAAACAGCAAAACCTGTAAGACATAAAGATAGAGTGGAG 4740
DB 996 GTCAAGTCAAAGCAAAACCAAAACAGCAAAACCTGTAAGACATAAAGATAGAGTGGAG 937
QY 4741 CCGACTGAGGATTAATTAAGTAACTAGATATTTTATTAACAGGCAATTTGAATTAATTT 4800
DB 936 CCGACTGAGGATTAATTAAGTAACTAGATATTTTATTAACAGGCAATTTGAATTAATTT 877
QY 4801 GTGCACCTTCAGAAATTTCTCAAAATATATATTTTCAATTTTAAATCTTTAAGAAA 4860
DB 876 GTGCACCTTCAGAAATTTCTCAAAATATATATTTTCAATTTTAAATCTTTAAGAAA 817
QY 4861 TTACTATATATATATATATATATATATATATATATATATATATATATATATATATAT 4920
DB 816 TTACTATATATATATATATATATATATATATATATATATATATATATATATATATAT 757
QY 4921 AGGTATATTTCTTTATTTCTGGGTGAGCAAGCTTCTAAGGGGATGTAAGGATATCT 4980
DB 756 AGGTATATTTCTTTATTTCTGGGTGAGCAAGCTTCTAAGGGGATGTAAGGATATCT 697
QY 4981 CTCTCTCTTCTAGTGAAGGATGAGTCTTAAAGTAAATATATATATATATATATATATAT 5040
DB 696 CTCTCTCTTCTAGTGAAGGATGAGTCTTAAAGTAAATATATATATATATATATATATAT 637
QY 5041 GTCTTTTGTATTTTGTGATTTGTGACCAACAGGGGCTTGGCTGAAGGGAATCTGAAGGG 5100
DB 637 GTCTTTTGTATTTTGTGATTTGTGACCAACAGGGGCTTGGCTGAAGGGAATCTGAAGGG 577
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QY 5101 CGGGGAGGGGGAATAGATGAAAAAACAACAAAAAACAACAAAAAACAACAAAAAACAAC 5160
DB 576 CGGGGAGGGGGAATAGATGAAAAAACAACAAAAAACAACAAAAAACAACAAAAAACAAC 517
QY 5161 ACAAAACATTTTAGCCCCCAGAAATAGTCAAGAAATCTCAAAATCTCAAAATCAAAACAGATTCAGA 5220
DB 516 ACAAAACATTTTAGCCCCCAGAAATAGTCAAGAAATCTCAAAATCTCAAAATCAAAACAGATTCAGA 457
QY 5221 TACAAGGAAGTGTATGAGCTGGAGCAGGGTGGACACTCATCATCTCAGCTCAGTTCAGTTTACA 5280
DB 456 TACAAGGAAGTGTATGAGCTGGAGCAGGGTGGACACTCATCATCTCAGCTCAGTTCAGTTTACA 397
QY 5281 AAAGTCCAGGCTGCTGAAATTAATTAATTAATTAATTAATTAATTAATTAATTAATTAAT 5340
DB 396 AAAGTCCAGGCTGCTGAAATTAATTAATTAATTAATTAATTAATTAATTAATTAATTAAT 337
QY 5341 GAGATCAGAAATTCAGAGATGCTCAGCTCCAGCTCCAAATTCGCAACAAACAAAGTGTGGCTACTA 5400
DB 336 GAGATCAGAAATTCAGAGATGCTCAGCTCCAGCTCCAAATTCGCAACAAACAAAGTGTGGCTACTA 277
QY 5401 TAGCTCAAGGACTCTCAAGCCGTGAGAGGGGGGAGAGCAACAGTAGAGAGAGTGCCTA 5460
DB 276 TAGCTCAAGGACTCTCAAGCCGTGAGAGGGGGGAGAGCAACAGTAGAGAGAGTGCCTA 217
QY 5461 GCTGGTAAAGAAATCGAGTGTATTAAGAGTTTGTAGTCAATTCATTCATTCATTCATTCAT 5520
DB 216 GCTGGTAAAGAAATCGAGTGTATTAAGAGTTTGTAGTCAATTCATTCATTCATTCATTCAT 157
QY 5521 TCAAGAAACGCTCCGCTCTCTTTGCAAAATATGATGAAGGAGAGAGTGCCTTAACTTCTA 5580
DB 156 TCAAGAAACGCTCCGCTCTCTTTGCAAAATATGATGAAGGAGAGAGTGCCTTAACTTCTA 97
QY 5581 TGCTCATAGCAATTTAGCCTTATGCTTTAGCTCCGCTTATATCTATATATATATATATAC 5640
DB 96 TGCTCATAGCAATTTAGCCTTATGCTTTAGCTCCGCTTATATCTATATATATATATAC 37
QY 5641 AGGTATTTGTATATATTTTATATATATATATATATATATATATATATATATATAT 5676
DB 36 AGGTATTTGTATATATTTTATATATATATATATATATATATATATATATATATAT 1
```

Alignment of seq 10 no: 1 w/ seq 10 no: 2

RESULT 4
US-10-030-294-2

Sequence 2: Application US/10030294
GENERAL INFORMATION:
APPLICANT: NIPPON KAYAKU KABUSHIKI KAISHA
TITLE OF INVENTION: Gene Encoding Promoter Region of Tumor Suppressor Gene p51
FILE REFERENCE: B5295-00
CURRENT APPLICATION NUMBER: US/10/030,294
CURRENT FILING DATE: 2001-12-27
PRIOR APPLICATION NUMBER: JP 11-183195
PRIOR FILING DATE: 1999-06-29
NUMBER OF SEQ ID NOS: 12

SEQ ID NO 2
LENGTH: 5960
TYPE: DNA
ORGANISM: Homo sapiens
FEATURE:
NAME/KEY: promoter
LOCATION: (1).(5676)
NAME/KEY: 5'UTR and intron
LOCATION: (5677).(5960)
US-10-030-294-2

Query Match 100.0%; Score 5676; DB 46; Length 5960;
Best Local Similarity 100.0%; Pred. No. 0;
Matches 5676; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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QY 1 CAGCTGTTCAGGAGTGTCTGAAAAAGAGCCCAACCTTCTCTGACACATCTGGGTGT 60
DB 1 CAGCTGTTCAGGAGTGTCTGAAAAAGAGCCCAACCTTCTCTGACACATCTGGGTGT 60
QY 61 GACTTTGGAGGTATCAGGTTTGTCTGTTAAAGAACTGCCAACCTCTTCTGCCCCAAT 120
```


4441 AGATGTGAACCTCACCATGTTAGTACCGTTAGATACACAGAGTGGTTTTTTTCCCTCCCTG 4500
4501 TTGGAGTCTATCCTTACCTGAGCTTCTGATCATATTTCAATTTCCAAATCCACAAA 4560
4501 TTGGAGTCTATCCTTACCTGAGCTTCTGATCATATTTCAATTTCCAAATCCACAAA 4560
4561 ACCAGGATAAGTTTACAGCCCATATTTAGAGAGGAAATATAATTTTGTGTGTAGACTT 4620
4561 ACCAGGATAAGTTTACAGCCCATATTTAGAGAGGAAATATAATTTTGTGTGTAGACTT 4620
4621 TCCTGATATTAACATGATTTGGGATATATGAGCAATTTTATGTTCTCTTCCGAGTAG 4680
4621 TCCTGATATTAACATGATTTGGGATATATGAGCAATTTTATGTTCTCTTCCGAGTAG 4680
4681 GTCAAGTCAAGCAAAACCAAAACAGCAAAACCTGTAAGACATATAAGATAGAGTGAG 4740
4681 GTCAAGTCAAGCAAAACCAAAACAGCAAAACCTGTAAGACATATAAGATAGAGTGAG 4740
4741 CCGACTGAGAGATTAATAAATAAAGTAAATATTTTATTAACAGGCAATTTGAAATATTT 4800
4741 CCGACTGAGAGATTAATAAATAAAGTAAATATTTTATTAACAGGCAATTTGAAATATTT 4800
4801 GTGCATCTCAGAAATATCTCAATATATATATTTTCCAAATTTTAAATATCTTAAAGAAA 4860
4801 GTGCATCTCAGAAATATCTCAATATATATATTTTCCAAATTTTAAATATCTTAAAGAAA 4860
4861 TTACTATATATATGATGATCATGTGATGATGATGATGATGATGATGATGATGATGAT 4920
4861 TTACTATATATATGATGATCATGTGATGATGATGATGATGATGATGATGATGATGAT 4920
4921 AGGTTATTTCTTTTATTCGGGTGAGCAAGCTTCTAAGGGGATGGAAGGATATCT 4980
4921 AGGTTATTTCTTTTATTCGGGTGAGCAAGCTTCTAAGGGGATGGAAGGATATCT 4980
4981 CTTTCTCTAGCTGAGAGGAGAGTGTGATGATGATGATGATGATGATGATGATGATGAT 5040
4981 CTTTCTCTAGCTGAGAGGAGAGTGTGATGATGATGATGATGATGATGATGATGATGAT 5040
5041 GTCTTTGCTATTTGAGATTTGACCAACAGCGGTTGGCTGAAGGGAACTGAAGGG 5100
5041 GTCTTTGCTATTTGAGATTTGACCAACAGCGGTTGGCTGAAGGGAACTGAAGGG 5100
5101 CGGGAGGGAGGAGGAAATAGATGAAACCAACCAACCAACCAACCAACCAACCAACCA 5160
5101 CGGGAGGGAGGAGGAAATAGATGAAACCAACCAACCAACCAACCAACCAACCAACCA 5160
5161 ACAAAACATTTTAGCCCCAGAGATGATGATGATGATGATGATGATGATGATGATGAT 5220
5161 ACAAAACATTTTAGCCCCAGAGATGATGATGATGATGATGATGATGATGATGATGAT 5220
5221 TACAAGGAGTGTATGATGATGATGATGATGATGATGATGATGATGATGATGATGAT 5280
5221 TACAAGGAGTGTATGATGATGATGATGATGATGATGATGATGATGATGATGATGAT 5280
5281 AAGTCCAGGCTGTGAAATTTAACTCTGATGATGATGATGATGATGATGATGATGATGAT 5340
5281 AAGTCCAGGCTGTGAAATTTAACTCTGATGATGATGATGATGATGATGATGATGATGAT 5340
5341 GAGATCAGAGATTTGAGAGTCTGATGATGATGATGATGATGATGATGATGATGATGAT 5400
5341 GAGATCAGAGATTTGAGAGTCTGATGATGATGATGATGATGATGATGATGATGATGAT 5400
5401 TAGCTCAAGGACTCTGAAGCGGTGAGAGGAGGAGGAGGAGGAGGAGGAGGAGGAGGAG 5460
5401 TAGCTCAAGGACTCTGAAGCGGTGAGAGGAGGAGGAGGAGGAGGAGGAGGAGGAGGAG 5460
5461 GCTGGTGAAGATCGAGTGTATGAGTGTATGAGTGTATGAGTGTATGAGTGTATGAGT 5520
5461 GCTGGTGAAGATCGAGTGTATGAGTGTATGAGTGTATGAGTGTATGAGTGTATGAGT 5520
5521 TCAGAAACCGCTCCGCTCTTTGCAATATGATGATGATGATGATGATGATGATGATGAT 5580

5521 TCAGAAACCGCTCCGCTCTTTGCAATATGATGATGATGATGATGATGATGATGATGAT 5580
5581 TGCTGATGATGATGATGATGATGATGATGATGATGATGATGATGATGATGATGATGAT 5640
5581 TGCTGATGATGATGATGATGATGATGATGATGATGATGATGATGATGATGATGATGAT 5640
5641 AGGTAATTTGATGATGATGATGATGATGATGATGATGATGATGATGATGATGATGAT 5676
5641 AGGTAATTTGATGATGATGATGATGATGATGATGATGATGATGATGATGATGATGAT 5676

RESULT 5
US-10-030-294-12
; Sequence 12, Application US/10030294
; GENERAL INFORMATION:
; APPLICANT: NIPPON KAYAKU KABUSHIKI KAISHA
; TITLE OF INVENTION: Gene Encoding Promoter Region of Tumor Suppressor Gene p51
; FILE REFERENCE: B5295-00
; CURRENT APPLICATION NUMBER: US/10/030,294
; CURRENT FILING DATE: 2001-12-27
; PRIOR APPLICATION NUMBER: JP 11-183195
; PRIOR FILING DATE: 1999-06-29
; NUMBER OF SEQ ID NOS: 12
; SEQ ID NO 1:
; LENGTH: 13340
; TYPE: DNA
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: Plasmid gene containing p51promoter and neomycin resistance gene
US-10-030-294-12

Query Match 100.0%; Score 5673.4; DB 46; Length 13940;
Best Local Similarity 100.0%; Pred. No. 0;
Matches 5674; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

QY 2 AGCTGTTTCAGGATGCTGCAAAAGAGAGCCCAACCAATTCCTTCTGGAACCTGGGTG 61
DB 51 ATCTGTTTCAGGATGCTGCAAAAGAGAGCCCAACCAATTCCTTCTGGAACCTGGGTG 110
QY 62 ACTTTGAGGGATATCAATGTTGCTGTTAAAGAAACCTGCCAATTCCTTCTGGAACCTGGGTG 121
DB 111 ACTTTGAGGGATATCAATGTTGCTGTTAAAGAAACCTGCCAATTCCTTCTGGAACCTGGGTG 170
QY 122 GGCTCTGTTTCCCTTGCATGCTCTTCTTCTGGAACCTGCCAATTCCTTCTGGAACCTGGGTG 181
DB 171 GGCTCTGTTTCCCTTGCATGCTCTTCTTCTGGAACCTGCCAATTCCTTCTGGAACCTGGGTG 230
QY 182 CATTAACCTTAACATATAATGTTTATTTGATGAAATTCAGTGACCTGAAGAGAGATGAGG 241
DB 231 CATTAACCTTAACATATAATGTTTATTTGATGAAATTCAGTGACCTGAAGAGAGATGAGG 290
QY 242 TCAAAATCAG 301
DB 291 TCAAAATCAG 350
QY 302 GTCAATTCGATACCAATTCAGTTTACCTTAACTTCTAGCCAGCTTTACTCTCTATTCGATG 361
DB 351 GTCAATTCGATACCAATTCAGTTTACCTTAACTTCTAGCCAGCTTTACTCTCTATTCGATG 410
QY 362 TCAGATCTGATGATATATTTAGGTCCTCAAGTTGGAAGAGATGATGATGATGATGATGATGAT 421
DB 411 TCAGATCTGATGATATATTTAGGTCCTCAAGTTGGAAGAGATGATGATGATGATGATGATGAT 470
QY 422 AGAATCTTGGCTTCCCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCT 481
DB 471 AGAATCTTGGCTTCCCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCT 530
QY 482 AGAATCTTGGCTTCCCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCT 541
DB 531 AGAATCTTGGCTTCCCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCT 590
QY 542 GGTGAATTTATCTCCACCACTCTCTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCTTCT 601